Docket No.: 3691-0133PUS1

## AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A process of preparing cells for cell therapy, comprising the steps of:

inducing <u>helper T</u> Th cells that have a nonspecific antitumor activity; and

imparting antigen specificity to the <u>helper T</u> Th cells

wherein the step of imparting antigen specificity to the helper T cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

## 2. (Cancelled)

- 3. (Currently Amended) The process for preparing cells for cell therapy according to claim 1, wherein the step of imparting antigen specificity to the <u>helper T</u> Th cells is carried out by transducing a gene for a class I-restricted <u>T cell receptor gene</u> TCR that recognizes a cancer-associated antigen.
- 4. (Currently Amended) The process for preparing cells for cell therapy according to claim 1, wherein the step of imparting antigen specificity to the <u>helper T</u> Th cells is carried out by transducing a gene for a class II-restricted <u>T cell receptor gene</u> TCR that recognizes a cancer-associated antigen.
- 5. (Currently Amended) The process for preparing cells for cell therapy according to any of claims 1, 3 or 4 2 to 4, wherein the cancer-associated antigen is selected from the group

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consisting of Wilms' Tumor 1 WT1, CEA, AFP, CA19-9, CA125, PSA, CA72-4, SCC, MK-1,

MUC-1, p53, HER2, G250, gp-100, MAGE, BAGE, SART, MART, MYCN, BCR-ABL, TRP,

LAGE, GAGE, and NY-ESO1.

6. (Currently Amended) The process for preparing cells for cell therapy according to

claim 1, wherein the step of inducing helper T Th cells having a nonspecific antitumor activity is

carried out by culturing a T cell-containing material in the presence of anti-CD3 antibody and

IL-2.

7. (Currently Amended) The process for preparing cells for cell therapy according to any

of claims 1, 3, 4 or 6 1 to 6, further comprising a step of purifying the helper T Th cells to which

antigen specificity has been imparted.

8. (Currently Amended) The process for preparing cells for cell therapy according to

claim 7, wherein the step of purifying the helper T Th cells to which antigen specificity has been

imparted is carried out by using antibody-bearing magnetic beads.

9. (Currently Amended) A process of preparing cells for cell therapy, comprising the

3

steps of:

inducing helper T 1 Th1 cells and cytotoxic T 1 Te1 cells that have a nonspecific

antitumor activity; and

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imparting antigen specificity to the <u>helper T 1 Th1</u> cells and <u>cytotoxic T 1 Te1</u> cells wherein the step of imparting antigen specificity to the helper T 1 cells and cytotoxic T 1 cells is

carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

10. (Cancelled)

11. (Currently Amended) The process for preparing cells for cell therapy according to

claim 9, wherein the step of imparting antigen specificity to the helper T 1 Th1 cells and

cytotoxic T 1 Te1 cells is carried out by transducing a gene for a class I-restricted T cell receptor

gene TCR that recognizes a cancer-associated antigen.

12. (Currently Amended) The process for preparing cells for cell therapy according to

claim 9, wherein the step of imparting antigen specificity to the helper T 1 Th1 cells and

cytotoxic T 1 Tel cells is carried out by transducing a gene for a class II-restricted T cell

receptor gene TCR that recognizes a cancer-associated antigen.

13. (Currently Amended) The process for preparing cells for cell therapy according to any

of claims 9 to 12-9, 11 or 12, wherein the cancer-associated antigen is selected from the group

consisting of Wilms' Tumor 1 WT1, CEA, AFP, CA19-9, CA125, PSA, CA72-4, SCC, MK-1,

MUC-1, p53, HER2, G250, gp-100, MAGE, BAGE, SART, MART, MYCN, BCR-ABL, TRP,

LAGE, GAGE, and NY-ESO1.

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14. (Currently Amended) The process for preparing cells for cell therapy according to claim 9, wherein the step of inducing helper T 1 Th1 cells and cytotoxic T 1 Te1 cells having a nonspecific antitumor activity is carried out by culturing a T cell-containing material in the presence of anti-CD3 antibody, IL-2, and IL-12.

- 15. (**Currently Amended**) The process for preparing cells for cell therapy according to any of claims 9, 11, 12 or 14 9 to 14, further comprising a step of separating the <u>helper T 1 Th1</u> cells and <u>cytotoxic T 1 Te1</u> cells to which antigen specificity has been imparted.
- 16. (**Currently Amended**) The process for preparing cells for cell therapy according to claim 15, wherein the process of separating the <u>helper T 1 Th1</u> cells and <u>cytotoxic T 1 Te1</u> cells to which antigen specificity has been imparted is carried out by using antibody-bearing magnetic beads.
- 17. (**Currently Amended**) The process for preparing cells for cell therapy according to claim 15—or—16, further comprising a step of mixing the separated <u>helper T 1</u> Th1 cells and <u>cytotoxic T 1</u> Te1 cells in any given proportion.
- 18. (Currently Amended) Cells for cell therapy, that are produced by a process comprising the steps of:

inducing helper T Th cells that have a nonspecific antitumor activity; and

imparting antigen specificity to the <u>helper T</u> Th cells, wherein the step of imparting antigen specificity to the helper T cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

19. (Currently Amended) Cells for cell therapy, that are produced by a process comprising the steps of:

inducing <u>helper T 1</u> Th1 cells and <u>cytotoxic T 1</u> Te1 cells that have a nonspecific antitumor activity; and

imparting antigen specificity to the <u>helper T 1</u> Th1 cells and <u>cytotoxic T 1</u> Te1 cells, wherein the step of imparting antigen specificity to the helper T 1 cells and cytotoxic T 1 cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

20. (Currently Amended) A method for preventing or treating tumor, comprising the steps of:

isolating leukocytes from a patient;

inducing from the leukocytes  $\underline{\text{helper }T}$   $\underline{\text{Th}}$  cells that have a nonspecific antitumor activity;

imparting antigen specificity to the <u>helper T</u> Th cells, wherein the step of imparting antigen specificity to the helper T cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen; and

administering to the patient the <u>helper T</u> Th cells to which antigen specificity has been imparted.

21. (Currently Amended) A method for preventing or treating tumor, comprising the steps of:

isolating leukocytes from a patient;

inducing from the leukocytes <u>helper T 1</u> Th1 cells and <u>cytotoxic T 1</u> Te1 cells that have a nonspecific antitumor activity;

imparting antigen specificity to the <u>helper T 1 Th1</u> cells and <u>cytotoxic T 1 Te1</u> cells, wherein the step of imparting antigen specificity to the helper T 1 cells and cytotoxic T 1 cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen; and administering to the patient the <u>helper T 1 Th1</u> cells and <u>cytotoxic T 1 Te1</u> cells to which antigen specificity has been imparted.